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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/787,548   | 05/29/2001  | Gunnar Grue-Sorensen | P 277978            | 2538             |
| 2292   | 7590        | 08/19/2004           | EXAMINER            |                  |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | BADIO, BARBARA P    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1616                |                  |

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |   |  |
|------------------------------|--|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/787,548       | <b>Applicant(s)</b><br>GRUE-SORENSEN ET AL. |  |
|                              | <b>Examiner</b><br>Barbara P. Badio, Ph.D. | <b>Art Unit</b><br>1616                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10-15 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-15 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 7, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 15 and 21 under 35 USC 112, second paragraph is withdrawn.

***Claim Rejections - 35 USC § 102***

4. The rejections of claims 1-6, 8, 10-15, 21 and 22 under 35 USC 102(b) over Calverley et al. (WO 91/15475 of '629) are maintained.

Applicant argues the claims are not anticipated because the cited references do not disclose all the elements of the claimed invention. Applicant's argument was considered but not persuasive for the following reasons.

According to applicant, hyperparathyroidism is completely different from the disease state of osteoporosis or related bone conditions although it may cause osteoporosis. Applicant also argues that there are several other completely independent causes of osteoporosis that may arise without hyperparathyroidism. However, the instant claims recite "osteoporosis and related bone conditions" and the art recognizes osteoporosis, osteomalacia and hyperparathyroidism as related bone disorders (see for example US patent No. 6,770,620, col. 6, lines 6-21; US Patent No. 6,395,740, col. 5, lines 23-27). Therefore, the claimed invention is anticipated by the cited prior art.

For this reason and those given in previous Office Action, the rejections of claims 1-6, 8, 10-15, 21 and 22 under 35 USC 102(b) over Calverley et al. (WO 91/15475 of '629) are maintained.

#### ***Claim Rejections - 35 USC § 103***

**5. The rejections of claims 1-6, 8, 10-15 and 21-23 under 35 USC 103(a) Calverley et al. (WO 91/15475 or '629) are maintained.**

Applicant argues the reference fail to disclose or suggest the claimed treatment method for several reasons. According to applicant, the references disclose treatment of hyperparathyroidism but do not state osteoporosis or related bone conditions.

Applicant also argues (a) hyperparathyroidism is separate from osteoporosis and (b) hyperparathyroidism may or may not lead to osteoporosis and, thus, treatment of hyperparathyroidism would not result in treatment of osteoporosis caused by other reasons.

In a declaration filed June 7, 2004, applicant states the correct description of bone related disease caused by hyperparathyroidism is not osteoporosis but osteomalacia. Applicant argues that because of the different etiologies between osteomalacia caused by hyperparathyroidism and osteoporosis, the diseases are treated differently and reference is made to an FDA publication on the guidelines for prevention or treatment of postmenopausal osteoporosis. According to applicant, the FDA guidelines do not mention or accept suppression of parathyroid hormone as a surrogate parameter for the efficacy of a new osteoporosis treatment compound. Applicant's argument was considered but not persuasive for the following reasons.

First, the art as stated above in #4 recognizes osteoporosis, osteomalacia and hyperparathyroidism as related bone disorders. The art also recognizes the use of similar agents for treatment of said disorders. In addition, the present specification discloses osteomalacia as related to osteoporosis and treatable utilizing the claimed compounds (see page 2 of the present specification, lines 11-13).

Secondly, although there are several underlining causes for osteoporosis, the instant claims are not limited to a specific cause and, thus, is inclusive of treatment of osteoporosis caused by hyperparathyroidism.

Lastly, the examiner did not reach the same conclusion after evaluation of the FDA publication. The article recognizes (a) osteoporosis may be associated with a variety of other disorders (see page 6, Introduction) and (b) the importance of serum parathyroid hormone levels by inclusion of a test of said hormone in the list of recommended tests for studying the pharmacodynamic action of a drug used in treating postmenopausal osteoporosis (see page 8, Phase II Studies). Secondly, the study population of the article is limited by excluding patients who have conditions that play a significant etiologic role in the development of osteoporosis (see page 10, Study population). However, limiting the study population does not imply that suppression of parathyroid hormone would not be effective in treatment of osteoporosis if the underlining cause of said osteoporosis is hyperparathyroidism. The skilled artisan reading the article would conclude based on the title of the article that the author was interested in **postmenopausal** osteoporosis and, thus, wanted to exclude from said study population patients having underlining causes not related to postmenopausal symptoms.


For these reasons and those given in previous Office Actions, the rejections of claims 1-6, 8, 10-15 and 21-23 under 35 USC 103(a) Calverley et al. (WO 91/15475 or '629) are maintained.

***Telephone Inquiry***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
August 18, 2004